

VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-030-D1					
		MEAN	RELATIVE STD. DEV.(%)	RANGE	SEE (conc)
ANALYTE	4-ABP				
MATRIX	Blood				
DATE	10-Aug-01				
LLOQ	(Provide Standard Concentration)	0.5 pg/g Hb. Accuracy 84.0% RSD 8.3%			
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))					
	1.5 pg/g Hb	Low QC			0.045
	100 pg/g Hb	Med QC			1.721
	350 pg/g Hb	High QC			6.463
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.)	Linear				
Slope (mean)	0.0174475				
Intercept (mean)	0.0014084				
Other (mean regression value)	0.999559(1/x weighted)				
RECOVERY (as a %)					
High QC in (matrix)=	350 pg/g Hb	90.90%			
Med QC in (matrix)=	100 pg/g Hb	70.70%			
Low QC in (matrix)=					
Results with different sample amounts (results of QC evaluations) Intra-assay					
LLOQ QC=	0.5 pg/g Hb	0.42	8.30%	0.37-0.46	0.014
Low QC=	1.5 pg/g Hb	1.39	3.30%	1.34-1.45	0.019
Med QC=	100 pg/g Hb	101.67	1.80%	99.48-104.37	0.764
High QC=	350 pg/g Hb	353.26	1.30%	344.33-356.78	1.845
Results with different sample amounts (results of QC evaluations) Inter-assay					
LLOQ QC=	n/a	n/a	n/a	n/a	n/a
Low QC=	1.5 pg/g Hb	1.47	7.60%	1.33-1.67	0.045
Med QC=	100 pg/g Hb	100.52	4.20%	90.07-105.10	1.721
High QC=	350 pg/g Hb	347.86	4.60%	318.97-370.59	6.463
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)		19.0% maximum			
b) Freeze/thaw (+/- % /3 cycles)		16.0% maximum			
c) Injector (+/- %/24 hrs)	300 hrs at nom. -20°C	2.7% maximum			